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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,950	01/29/2004	Tony N. Aram	4004-001	1850

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EXAMINER

HOFFMAN, MARY C

ART UNIT	PAPER NUMBER
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3733

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/765,950	Applicant(s) ARAM, TONY N.	
	Examiner Mary Hoffman	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1/29/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13-23, 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vanderwalle (U.S. Patent 5,993,452) in view of Florio (U.S. Patent 3,469,573).

Vanderwalle discloses embodiments of a method for stabilizing and facilitating recovery of injured bone within a living body, the method comprising providing a surgical instrument (FIG. 1, ref. #7) comprising a flexible cable (see FIG. 1, ref. #18) and a plurality of bone-contacting enlargements (FIG. 1, ref. #28), the flexible cable having a first end, a second end, and a length sufficient to wrap around the injured bone, the bone-contacting enlargements being fixedly attached to the flexible cable between the first and second ends and being spaced apart from one another to provide linking cable portions alternating with the spaced bone-contacting enlargements; passing the surgical instrument about the injured bone to contact the bone-contacting enlargements and the injured bone with one another, the bone-contacting enlargements positioning the linking cable portions in spaced relationship to the injured bone, tensioning the flexible cable about a region of the injured bone to constrict the region while the bone-contacting enlargements retain the linking cable portions in spaced relationship to the injured bone

Art Unit: 3733

for permitting vascular communication across the constricted region of the injured bone; and securing surgical instrument about the injured bone. The flexible cable is formed of a metal (col. 2, last paragraph). The flexible cable is formed of a metal selected from stainless steel and cobalt chrome (col. 2, last paragraph). The flexible cable is axially inelastic. The bone-contacting enlargements are obtuse, i.e. blunt and non-pointed. The bone-contacting enlargements comprise beads. The bone-contacting enlargements have peripheries circumferentially surrounding the flexible cable. The bone-contacting enlargements each have a respective axial length smaller in dimension than respective axial lengths of adjacent ones of the linking cable portions (see FIG. 6). The method includes providing a connecting device (FIG. 1, ref. #10, FIG. 6, ref. #66) and securing surgical instrument about the injured bone via the connecting device. The step of passing further includes feeding the flexible cable, with the bone-contacting enlargements being fixedly attached thereto, about the injured bone to arrange the flexible cable in a loop and to encircle the bone-contacting enlargements about the injured bone (see FIG. 1, FIG. 6). The step of passing further includes feeding the flexible cable, with the bone-contacting enlargements being fixedly attached thereto, about the injured bone a plurality of times to arrange the flexible cable in a coil and to position the bone-contacting enlargements about the bone (FIG. 11). The bone-contacting enlargements have peripheries that circumferentially surround the flexible cable.

Art Unit: 3733

Vanderwalle discloses the claimed invention except for the bone-contacting enlargements being permanent and comprising a metal or a high molecular weight polymer, specifically polyethylene.

Florio discloses using bone-contacting enlargements that are permanent in order to improve the growth and development of fibrous tissue, blood vessels, etc. to grow through the device (col. 2, first paragraph+).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Vanderwalle with the bone-contacting enlargements being permanent in view of Florio to improve the growth and development of fibrous tissue, blood vessels, etc. to grow through the device. It would have further been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Vanderwalle in view of Florio including the bone-contacting enlargements comprising metal or a high molecular weight polymer, specifically polyethylene, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claims 24-30 and 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vanderwalle (U.S Patent 5,993,452) in view of Florio (U.S. Patent 3,469,573) further in view of Kipela et al. (U.S. Patent No. 6,595,994).

Vanderwalle in view of Florio discloses the claimed invention except for the method further comprising engaging a tensioning device to the second end portion and tensioning the flexible cable about a region of injured bone to constrict the region.

Art Unit: 3733

Kipela et al. (U.S. Patent No. 6,595,994) disclose a method comprising engaging a tensioning device to the second end portion and tensioning the flexible cable about a region of injured bone to constrict the region when there is a need to penetrate into small deep wounds and incisions for tensioning cables deeply mounted in the body (col. 1, lines 20-25).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of Vanderwalle in view of Florio including the tensioning device in view of Kipela et al. (U.S. Patent No. 6,595,994) when there is a need to penetrate into small deep wounds and incisions for tensioning cables deeply mounted in the body

Claims 31-35 and 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vanderwalle (U.S. Patent 5,993,452) in view of Florio (U.S. Patent 3,469,573) further in view of Kipela et al. (U.S. Patent No. 5,414,658).

Vanderwalle in view of Florio discloses the claimed invention except for the method further comprising a connecting device that can be used in crimping the first end of the flexible cable to a truncated cable portion of the connecting device, and feeding the second end of the flexible cable through a receiving region of the connecting device, and the connecting device comprising a crimpable body portion for receiving and crimping with the first end of the flexible cable; and the connecting device comprising a first screw for securing the first end of the flexible cable to the connecting device, and a second screw for securing the second end of the flexible cable to the connecting device.

Kipela et al. (U.S. Patent No. 5,414,658) disclose a method for using a connecting device (see FIGS. 1-3) comprising a connecting device used in crimping the first end of the flexible cable to a truncated cable portion of the connecting device, and feeding the second end of the flexible cable through a receiving region of the connecting device, and the connecting device comprising a crimpable body portion for receiving and crimping with the first end of the flexible cable; and the connecting device comprising a first screw for securing the first end of the flexible cable to the connecting device, and a second screw for securing the second end of the flexible cable to the connecting device which is to be used in lieu of the prior art to provide an essentially foolproof technique of cable securance (col. 1, lines 56-57).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of Vanderwalle in view of Florio including using the a connecting device and method of crimping the first end of the flexible cable to a truncated cable portion of the connecting device, and feeding the second end of the flexible cable through a receiving region of the connecting device, and the connecting device comprising a crimpable body portion for receiving and crimping with the first end of the flexible cable; and the connecting device comprising a first screw for securing the first end of the flexible cable to the connecting device, and a second screw for securing the second end of the flexible cable to the connecting device in view of Kipela et al. (U.S. Patent No. 5,414,658) to provide an essentially foolproof technique of cable securance.

Response to Arguments

Applicant's arguments, see page 10 of Remarks, lines 4-9, filed 12/11/2006, with respect to claims 13, 24, 31, and dependents have been fully considered and are persuasive. In particular, the examiner agrees that ref. #2 of Clarenz is a strap, belt, or band, and is not a "flexible cable" required by the claims. The rejections of the claims as being anticipated by German Patent 32 44 680 to Clarenz have been withdrawn.

Applicant's arguments, see page 11 of Remarks, lines 5-9, filed 12/11/2006, with respect to claims 13, 24, 31, and dependents have been fully considered and are persuasive. In particular, the examiner agrees that ref. #10 of Gundolf is a strap, belt, or band, and is not a "flexible cable" required by the claims. The rejections of the claims as being anticipated by U.S. Patent 5,571,105 to Gundolf have been withdrawn.

Applicant's arguments filed 12/11/2006 regarding the 103(a) rejections (i.e. over Vanderwalle (U.S. Patent 5,993,452) in view of Florio (U.S. Patent 3,469,573), further in view of Kipela et al. (U.S. Patent No. 6,595,994), and further in view of Kipela et al. (U.S. Patent No. 5,414,658) have been fully considered but they are not persuasive.

Applicant states that the Vanderwalle reference discloses a cerclage system using bioresorbable bone-contacting enlargements, or jackets ref. #28, that allow the device to slowly loosen its fit around the injured bone as the bioresorbable bone-contacting enlargements are gradually resorbed into the body. Applicant argues that the bioresorbable bone-contacting enlargements are the crux of the invention, therefore, any modification of the bone-contacting enlargements to be permanent rather than temporary, i.e. bioresorbable, would constitute hindsight and also teaches away from

Art Unit: 3733

the invention of Vanderwalle. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). It was well-known in the field of medical devices at the time the claimed invention was made that devices made with bioresorbable materials are an improvement over devices formerly made with non-bioresorbable metals and plastics. Bioresorbable materials have been applied to many well-known medical device technologies and applications, including bone cerclage. However, it is the examiner's opinion that it would not be considered "teaching away" to take the device of Vanderwalle, which includes bioresorbable bone-contacting enlargements, and construct them from a non-bioresorbable material in view of Florio, since non-bioresorbable devices and components are in fact the predecessors of bioresorbable devices and components. Moreover, the examiner would like to point out that in column 4, lines 30-40, the Vanderwalle reference actually compares one of its embodiments that employs bioresorbable spacers to an earlier invention that uses similar non-bioresorbable spacers (Bailey U.S. Patent No. 5,607,430). Therefore, the Vanderwalle reference itself shows that spacers/bone-contacting enlargements can be either bioresorbable or non-bioresorbable, despite the fact that the reference teaches that bioresorbable materials

Art Unit: 3733

have many advantages, including preventing necrosis and bone growth around the device. Applicant also asserts that a person of ordinary skill in the art at the time the invention was made would have no reasonable expectation success in combining the two patents, since the device of Florio acknowledges that it does not overcome the problems addressed by Vanderwalle, i.e. to prevent necrosis and bone growth around the device. The examiner disagrees that there is no reasonable expectation of success to incorporate the permanent material of the bone contacting enlargements of Florio into the bone-contacting enlargements of Vanderwalle. Clearly, these two references are both directed to bone cerclage devices that secure the portions of a fractured bone together during bone growth and healing while reducing the area of pressurized contact between the device and the bone. Moreover, as already discussed above, the Vanderwalle shows evidence (the Bailey patent incorporated by reference) that bioresorbable materials have been used to previously replace non-bioresorbable components in bone cerclage devices. Applicant further asserts that the combination of Vanderwalle and Florio would not render the claims obvious, since the bone-contacting enlargements of Florio do not have peripheries circumferentially surrounding the flexible cable. The examiner respectfully disagrees, since it is stated in the above rejections that Vanderwalle (not Florio) discloses bone-contacting enlargements with peripheries circumferentially surrounding the flexible cable. The rejection further states that "Vanderwalle discloses the claimed invention except for the bone-contacting enlargements being permanent" and later states that "Florio discloses using bone-contacting enlargements that are permanent ...". In other words, the Florio

Art Unit: 3733

reference is merely being used to show that the prior art anticipates using permanent bone contacting enlargements with bone cerclage devices. Therefore, the examiner respectfully disagrees and maintains that the combination of the two references contains all the claim limitations, thus rendering the claims obvious.

The rejections are deemed proper.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone

Art Unit: 3733

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MCH



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SUPERVISORY PATENT EXAMINER